

**REMARKS**

Claims herein under examination are claims 7-11 and newly added claims 19-24.

Claims 7, 10, and 11 have been amended; no new matter has been added by these amendments. Claim 7 was amended to independent form. Support for the amendment to claim 7 is found throughout the application and particularly in claim 4; p. 17, lines 26-27; and p. 36, lines 3-5. Support for the amendment to claim 10 is found throughout the application and particularly at p. 41, lines 7-25. Claim 11 was amended to independent form. Support for the amendment to claim 11 is found throughout the application and particularly at p. 43, line 30 - p. 44, line 12.

Claims 19-24 have been newly added by this amendment. Support for claim 19 can be found throughout the application and particularly at p. 17, lines 15-21; p. 36, lines 15-27. Support for claim 20 can be found throughout the application and particularly at p. 36, lines 3-7. Support for claim 21 can be found throughout the application and particularly at p. 36, lines 6-7, lines 20-22. Support for claim 22 can be found throughout the application and particularly at p. 36, line 5. Support for claims 23 and 24 can be found throughout the application and particularly at p. 18, lines 19-27 and at p. 41, lines 7-24, respectively.

As such, no new matter has been added.

**Rejection Under 35 U.S.C. 112, Second Paragraph**

Claims 7-11 have been rejected under 35 U.S.C. 112, second paragraph, as being indefinite because they depend from non-elected claim 4. Applicants respectfully traverse this rejection.

Claim 7 has been written in independent form. As such, claim 7 and the claims dependent therefrom no longer depend from a non-elected claim. Applicants request removal of this rejection.

**Rejection Under 35 U.S.C. 102(b)**

Claims 7-10 have been rejected under 35 U. S. C. 102(b) as being anticipated by Altman et al. Science (1996)274: 94-96). The Examiner states that Altman et al teach a polynucleotide comprising a nucleotide sequence encoding a fusion polypeptide comprising a T cell antigen presenting domain (HLA-A2)fused to an oligomerization domain (a 15 amino acid substrate peptide for BirA dependent biotinylation). Additionally, the Examiner states that Altman et al teach a gene delivery vehicle and a host cell comprising said nucleotide. Claim 10 was included in the rejection since the host cell comprising said nucleotide expresses the fusion protein encoded by said nucleotide. Applicants respectfully traverse this rejection as follows.

In contrast to the instant invention as claimed, Altman et al. does not teach a polynucleotide encoding a fusion polypeptide comprising a T cell antigen presenting domain fused to an oligomerization domain. The polynucleotide taught by Altman encodes for a T cell antigen presenting domain fused to an oligomerization precursor domain. This oligomerization precursor domain comprises a 15 amino acid substrate peptide for BirA dependent biotinylation, as noted by the Examiner. Importantly, unlike the instant invention, translation of the polynucleotide taught in Altman produces a fusion polypeptide that cannot oligomerize. Oligomerization can only occur by performing a biochemical modification to add the vitamin, biotin. Indeed, these manipulations are taught away from in the instant application (p. 34, lines 21-30). The present invention is novel over Altman's method by providing a polynucleotide encoding for both a T cell antigen presenting domain and an oligomerization domain. With these two elements, the instant invention eliminates the requirement for problematic biochemical modifications.

Finally, Altman et al. teach an oligomerization molecule, biotin, that cannot be translated into a nucleic acid sequence. Therefore, it is clear that the polynucleotide taught by Altman does not and also cannot have the encoded oligomerization domain that is required by the claimed invention. Since this feature is not present in the Altman, the reference therefore cannot anticipate the instant invention. Claims 8-10 also cannot be anticipated by the polynucleotide taught in Altman for the reasons presented above. Accordingly, we respectfully request that these rejections be withdrawn for all claims.

**Rejection Under 35 U.S.C. 102(a) and/or (e)**

Claims 7-11 have been rejected under 35 U. S. C. 102(a) and/or (e) as being anticipated by Schneck et al. US Patent 6,015,884. The Examiner states that '884 teaches a polynucleotide comprising a nucleotide sequence encoding a fusion polypeptide comprising a T cell antigen presenting domain (NHC Class II fused to peptide antigen) fused to an oligomerization domain (immunoglobulin heavy and light chains), a gene delivery vehicle and a host cell comprising said nucleotide. Claim 10 was included in the rejection since the host cell comprising said nucleotide expresses the fusion protein encoded by said nucleotide. Applicants traverse this rejection as follows.

Schneck et al. teach a polynucleotide comprising a nucleotide sequence encoding a fusion polypeptide comprising a T cell antigen presenting domain (NHC Class II fused to peptide antigen) fused to a heterodimeric oligomerization domain. This polynucleotide taught by Schneck encodes two separate polypeptide chains in the form of immunoglobulin heavy and light chains, ('884, col. 11, lines 29-30). The translation of the polynucleotide to produce the fusion polypeptide will necessarily produce a heterodimeric molecule. This is in contrast to claim 7, which teaches a polynucleotide encoding a fusion polypeptide capable of forming a stable homomultimer (see p. 17, lines 26-27; p. 36, lines 3-5). Schneck neither teaches nor suggests the use of an oligomerization domain to form homomultimers. Rather, every embodiment taught by Schneck utilizes at least two separate polypeptide chains to form a heterodimeric molecule. Applicants have emphasized the homomeric nature of the instant invention over the heteromeric requirement in Schneck by clarifying this feature in claim 7. Applicants request that this rejection be removed from claims 7-10, and newly added dependent claim 22.

Additionally, Applicants assert that Schneck does not anticipate claim 11. Schneck et al teaches the expression of heterodimeric proteins using a recombinant baculovirus system. However, Schneck does not teach or suggest the use of a second polynucleotide, which encodes for a T cell epitope, in the same recombinant cell that contains the polynucleotide encoding for the fusion polypeptide. This second

polynucleotide, which encodes for a T cell epitope, is required by step (ii) of claim 11. Also, see p. 43, line 30 - p. 44, line 12. Therefore, Schneck cannot anticipate claim 11. Accordingly, we respectfully request that this rejection be withdrawn.

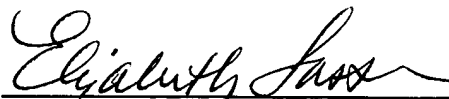
New claim 19 has been added which is drawn to another embodiment of the instant invention. Applicants respectfully submit that Schneck does not anticipate this newly added claim. Schneck teaches a polynucleotide encoding a heterodimeric oligomerization domain wherein the translated polypeptide chains bind together to form a heterodimeric molecule. This teaching contrasts with the instant invention of claim 19. In steps a) and b), claim 19 requires a polynucleotide comprising an oligomerization domain, which a) does not bind to itself and b) will bind to a multivalent platform molecule to form stable multimers. Schneck neither teaches nor suggests the use of an oligomerization domain that does not bind to itself. In fact, Schneck teaches away from the use of such a domain as the heterodimeric molecules provided in Schneck could not form if the proteins did not associate with each other. In addition, Schneck neither teaches nor suggests the use of an oligomerization domain capable of binding to a multivalent platform molecule. As such, Schneck cannot anticipate newly added claim 19 nor those that depend therefrom.

No fee is deemed necessary in connection with the filing of this communication. However, if any fee is required, authorization is hereby given to charge the amount of any such fee to Deposit Account No. 07-1074.

Respectfully submitted,

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Date



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